REMARKS

Claims 1-5, 7-9, 11-13, 15-23, 30, 50, 51, 55, 58-61, 64, 67-86, 88, 90, 92, and 94 are currently pending. Claims 4 and 5 are amended herein. Claim 90 has been canceled. Therefore claims 1-5, 7-9, 11-13, 15-23, 30, 50, 51, 55, 58-61, 64, 67-86, 88, 92, and 94 are under consideration. Claims 4 and 5 have been amended to recite "the composition of claim 1" in the preamble. Although this amendment appears completely unnecessary given the original preamble referring to the hinge region of claim 1 which is a component of the composition, given the Examiner's restriction of the hinge region as a separate group III, Applicants wanted to make it abundantly clear the claims 4, 5, and their dependencies merely define a region claimed in claim 1. Claim 90 has been canceled as a redundant claim. Applicants believe that the amendments raise no new issues and do not constitute new matter.

The PTO requires the restriction of the claims in the above-identified application into one of the following four groups of claims.

Group I: Claims 1, 2, 7-9, 11-13, 15-23, 30, 86, 88, 90, 92, and 94 allegedly drawn to a first and second DNA binding domains separated by a hinge domain.

Group II: Claims 3 (in part), 50, 51, 55, 58, and 59 allegedly drawn to a first and second DNA binding domains separated by a hinge domain and further comprising an activation domain.

Group III: Claims 4 and 5 allegedly drawn to a hinge domain.

Group IV: Claims 3 (in part), 60, 61, 64, 67, and 68 allegedly drawn to a first and second DNA binding domains separated by a hinge domain and further comprising a repressor domain.

Group V: Claims 69-71 and 73, allegedly drawn to a nucleic acid encoding the composition of Group I, vectors, and cells comprising the nucleic acid.

Group VI: Claims 72 and 74, allegedly drawn to animals comprising the cells of Group V.

Group VII: Claim 75, allegedly drawn to a method of identifying a gene under control of a hormone response element by contacting a cell with the composition of Group I.

Group VIII: Claim 76, allegedly drawn to a method of identifying a gene under control of a hormone response element by contacting a cell with the composition of Group II.

Group IX: Claim 77, allegedly drawn to a method of identifying a gene under control of a hormone response element by contacting a cell with the composition of Group IV.

Group X: Claims 78 and 84, allegedly drawn to a method of treating cancer by administration of the composition of Group I.

Group XI: Claim 79, allegedly drawn to a method of treating cancer by administration of the composition of Group IV.

Group XII: Claims 80-82, allegedly drawn to methods of inhibiting the transcription of a gene by contacting a cell with the composition of Group IV.

Group XIII: Claim 83, allegedly drawn to a method of overexpressing a gene in a cell by contacting the gene with the composition of Group II.

Group XIV: Claim 85, allegedly drawn to a method of treating cancer by administration of the composition of Group II.

Applicants provisionally elect Group I with traverse.

Due to the provisional election of Group I, Applicants have a further restriction among the sequences in Claims 16-19, 30, 86, 88, 90, 92, and 94. The Examiner alleges that one sequence must be elected as a separate restriction between the DNA binding sites of SEQ ID NOS: 1-22 in claims 16-19 and 30; between the DNA binding domains of SEQ ID NOS: 23, 25, 27, 29, 31, 33, 35, 37, and 39 in claims 86, 88, and 90; and the hinge regions of SEQ ID NOS: 24, 26, 28, 30, 32, 34, 36, 38, and 40 in claims 92 and 94. Applicants provisionally elect SEQ ID NO: 9 for claims 16-19 and 30; SEQ ID NO: 23 for claims 86, 88, and 90; SEQ ID NO: 24 for claims 92 and 94.

37 C.F.R. § 1.475 provides that national stage applications shall relate to one invention or to a group of inventions so linked as to form a single general inventive concept. Such inventions possess unity of invention. The requirement of a single inventive concept is fulfilled when there

is a technical relationship within the claimed subject matter involving one or more of the same or corresponding special technical features. The special technical feature must define a contribution that the claimed subject matter makes over the prior art.

Applicants note that the claims all a composition comprising the formula W-Z-X wherein W comprises a first DNA binding domain, X comprises a second DNA binding domain, and Z comprises a hinge domain, and wherein the composition binds a DNA binding site, and that this limitation constitutes a special technical feature that defines a contribution that the claimed subject matter makes over the prior art. Thus, the pending claims all have the same corresponding technical feature. Applicants respectfully remind the Examiner that PCT Rule 13.2 states that

> the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In providing the restriction requirement, the Examiner alleges that Muyan et al. (2001) Mol and Cell. Endocrinology 182: 249-263 teaches the claimed technical feature. The Examiner points to Figure 1 of Muyan et al as disclosing the claimed composition (see page 3 of the present restriction). Applicants respectfully point out that Muyan et al. discloses a homofusion of ERα. As noted in the abstract of Muyan, the ERα homofusion is not a DNA binding domain, but a single chain receptor. Applicants concede that within ERα there exists a DNA binding domain and a hinge domain. However, claim 1 recites that the composition comprises the formula of W-Z-X wherein W is a first DNA binding domain, Z is a hinge, and X is a second DNA binding domain. The ERα homofusion comprises all of the components of two intact ERα receptors and therefore, Muyan does not comprise this formula. In fact, no reading of Muyan et al. would arrive at the claimed formula. For this reason alone, the art cited by the Examiner neither anticipates nor renders obvious the special technical feature of the invention. Applicants respectfully point out that the Examiner has not provided any evidence that any disclosure exists in the art that would destroy the novelty or inventive step of this common technical feature and

thereby destroy single the inventive concept. Thus, the Examiner has not met his burden for establishing a lack of unity of invention. Accordingly, Applicants submit that all of the pending claims possess unity of invention.

Furthermore, because all of the claims, by virtue of their dependency on claim 1, posses a common technical feature which makes a contribution over the prior art, then need to elect a sequence for a DNA binding site, first and second DNA binding domain, and hinge domain in claims 16-19, 30, 86, 88, 90, 92, and 94 is rendered moot. Further restriction can not be required because the common technical feature possessed by the claims is a composition comprising the formula of W-Z-X wherein W is a first DNA binding domain, Z is a hinge, and X is a second DNA binding domain. Moreover, Applicants respectfully point out that the further restrictions required by the Examiner are in some cases nonsensical at best and inoperable at worst as the election in some cases would require only a single half site to of a DNA binding site be known and prevent combinations using the very same half site. Furthermore, first and second DNA binding domains would be forced to be the same preventing the formation of heterodimers. Thus the election even if operable prevent the contemplation of heterodimers from ever being prosecuted. Additionally, the further restriction is inconsistent with one of the policies behind restriction which is to promote efficient prosecution and not creating overly burdensome searches for the Examiner. If the further restrictions stand, this would promote inefficiency as each and every combination of DNA binding site, DNA binding domain, and hinge domain would need to be separately prosecuted. This one not only slow-down prosecution but be prohibitively expensive to the applicant. At best, the further restrictions at best would be a species election. However, in that case, Applicants remind the Examiner that Applicants would be allowed to prosecute a reasonable number of species.

Applicants also point out that claims 4 and 5 have been amended to remove any confusion as to what is meant by the claims. Applicants do not understand how a claim further defining a limitation of a base claim could be further restricted into an entirely different group. Nevertheless, to clear up any confusion, the preamble of claims 4 and 5 has been amended.

Applicants respectfully request that Group III be rejoined with Group I in light of Applicants' amendment.

Additionally, Applicants respectfully submit that rule 37 C.F.R. § 1.475(b) states that "claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations [emphasis added]." Applicants note that one of the combinations explicitly enumerated in 37 C.F.R. § 1.475(b)(2) is a product and process of use of said product. Thus, under 37 C.F.R. § 1.475(b)(2) Applicants care entitled to unity of invention for at least a product and a process of use irregardless of whether unity of invention is found for all the claims. Accordingly and not withstanding the above arguments for the presence of unity of invention, Applicants request the rejoinder of Group X to Group I.

Applicants respectfully remind the Examiner that the correct standard for determining unity of invention is stated in rule 37 C.F.R. § 1.475(a). This rule, as well as the Rule 37 C.F.R. § 1.475(b)-(e), are consistent with PCT Rule 13.2, which provides the exclusive standard for determining unity of invention in national stage applications.

Moreover, Applicants respectfully point out that the application provides only 1 independent claim. PCT Rule 13.4 states that:

> it shall be permitted to include in the same international application a reasonable number of dependent claims, claiming specific forms of the invention claimed in an independent claim, even where the features of any dependent claim could be considered as constituting in themselves an invention.

In fact, according to MPEP 1850, "unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. [emphasis added]" Moreover, it is stated in MPEP 1850 that "[i]f the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention." Therefore, because there is only a single independent claim which includes a special technical feature which defines a contribution over the prior art, and because all of the remaining claims possess this technical feature by virtue of there dependency on said independent claims, all the pending claims possess unity of invention.

Thus, the present restriction requirement is improper and must be withdrawn. Accordingly, applicants respectfully request rejoinder and examination of all of the claims.

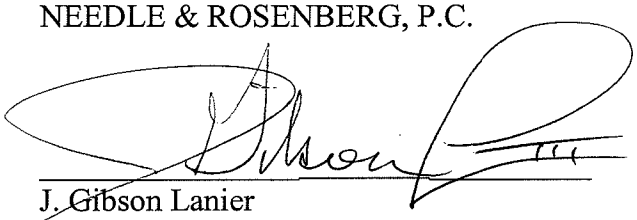
Lastly, because unity of invention exists and in light of traditional U.S. restriction practices, Applicants remind the Examiner that restriction under traditional U.S. practice is only appropriate where a search for more than one group would create an undue burden for the Examiner. Applicants respectfully point out that a search for the composition of claim 1, would necessarily comprise a search for Group II which has all the features of Group I in addition to the presence of an activation or repressor domain. Therefore, no additional burden would be placed upon the Examiner as no additional search would be needed. For at least this reason and the reasons stated above, Group II should be rejoined with Group I.

For the above reasons, reconsideration or withdrawal of the restriction requirement is requested.

A credit card payment submitted via EFS Web in the amount of $1,115.00, representing the fee for a small entity under 37 C.F.R. § 1.17(a)(5) and a five (5) month Extension of Time are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.



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